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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/033,692 | 12/21/2001 | Renzo Dal Molin | 8707.2135 | 8583 |

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10/19/2004

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| EXAMINER |
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MULLEN, KRISTEN DROESCH

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| ART UNIT | PAPER NUMBER |
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3762

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,692

Applicant(s)

MOLIN, RENZO DAL

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 10-12 is/are rejected.
- 7) ☒ Claim(s) 3 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. In page 7, second paragraph of Applicant's response Applicant states that a true and correct copy of the change of inventorship document submitted to the French Patent Office was submitted. This document has not been received.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

3. Claims 1-12 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. A question of inventorship arises due to the inventor named in the foreign priority document (French Patent Application No. 00 16906) being inconsistent with the inventorship (as amended) of this application.

4. Claims 1-2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Baura (6,058,325).

Regarding claim 1, Baura shows a process for measuring the complex impedance of a lead comprising discharging a tank capacitor (180) to produce a stimulation pulse; measuring a voltage variation $V_{out}(k)$ at the terminals of the tank capacitor during the discharge; and determining the lead impedance based on the measured voltage comprising sampling at least three successive values of the voltage ($V_{out}(k)$ is collected at

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20 KHz) at the tank capacitor terminals; and determining separately a resistive component (R) and a capacitive component (C) of the impedance from the sampled values (Col. 14, line 52- Col. 15, line 64; Figs. 7-8).

With respect to claim 2, Baura shows the determination is operated by an algebraic calculation (Equations 28, 29).

Regarding claim 4, Baura shows sampling the at least three successive values further comprises sampling the at least three successive values during the same pulse (Col. 15, lines 24-30).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baura (6,058,325). Baura is as explained before.

With respect to claims 5-6, Baura discloses the claimed invention except for sampling at least three successive values during two successive stimulation pulses with the second pulse having twice the duration of the first pulse and sampling the first time at the beginning of the first pulse sampling the second time at the end of the first pulse and sampling the third time at the end of the second pulse. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the timing of the sampling as taught by Baura with sampling at least three successive values during two successive stimulation pulses with the second pulse having

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twice the duration of the first pulse and sampling the first time at the beginning of the first pulse sampling the second time at the end of the first pulse and sampling the third time at the end of the second pulse, since applicant has not disclosed that this particular timing of sampling provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any timing of sampling such as sampling at 1000 Hz or less with optional decimation taught by Baura for sampling the voltage and determining the resistive and capacitive components of lead impedance.

7. Claims 7-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baura (6,058,325) in view of Busch et al. (6,304,781). Baura shows a device including means for discharging a tank capacitor (180) to produce a stimulation pulse; means for measuring a voltage variation $V_{out}(k)$ measuring a voltage variation at the terminals of the tank capacitor during the discharge; and means for determining the lead impedance based on the measured voltage comprising means for sampling at least three successive values of the voltage ($V_{out}(k)$ is collected at 20 KHz or less and optionally decimated) at the tank capacitor terminals; and means for determining separately a resistive component (R) and a capacitive component (C) of the impedance from the sampled values (Col. 14, line 52- Col. 15, line 64; Figs. 7-8). Although Baura fails to show the device is an implantable medical device, attention is directed to Busch et al. which teaches an implantable medical device that measures the capacitive impedance of electrodes. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Baura to be an implantable medical device since Busch et al shows it is also desirable to measure the impedance (and its components) of electrodes associated with an implantable medical device.

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With respect to claim 8, Baura shows the determination means comprises an algebraic calculation (Equations 28, 29).

Regarding claim 10, Baura shows the sampling means further comprises sampling the at least three successive values during the same stimulation pulse (Col. 15, lines 24-30).

Regarding claims 11-12, Baura and Busch et al. disclose the claimed invention except for sampling at least three successive values during two successive stimulation pulses with the second pulse having twice the duration of the first pulse and sampling the first time at the beginning of the first pulse sampling the second time at the end of the first pulse and sampling the third time at the end of the second pulse. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the timing of the sampling as taught by Baura and Busch et al. with sampling at least three successive values during two successive stimulation pulses with the second pulse having twice the duration of the first pulse and sampling the first time at the beginning of the first pulse sampling the second time at the end of the first pulse and sampling the third time at the end of the second pulse, since applicant has not disclosed that this particular timing of sampling provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any timing of sampling such as sampling at 1000 Hz or less with optional decimation taught by Baura and Busch et al. for sampling the voltage and determining the resistive and capacitive components of lead impedance.

Response to Arguments

8. Applicant's arguments filed 7/12/04 have been fully considered but they are not persuasive.

9. In response to applicant's arguments that the Baura reference does not anticipate either claim 1 or claim 7 because it does not teach or suggest discharging the tank-capacitor to produce a stimulation pulse on the lead, measuring a voltage variation ($V(t)$) at the terminals of the tank-capacitor during said discharge and determining separately a resistive component (R_s) and a capacitive component (C_H) of the impedance of the lead from said at least three sampled values of voltage, the examiner disagrees. Baura shows discharging a tank capacitor (180), measuring a voltage variation (V_{outk}) at the terminals of the tank capacitor and determining the resistive component and capacitive component separately from at least three sampled values of voltage (sampled at 20KHz). Baura shows the resistance is first calculated and then the capacitance is calculated. The claim language does not require the resistance and capacitance to be calculated independently of one another.

10. Applicant's arguments, see page 9 of Applicant's response, filed 7/12/04, with respect to claims 3, and 9 have been fully considered and are persuasive. The rejections of claims 3, and 9 have been withdrawn.

Allowable Subject Matter

11. Claims 3 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen (formerly Droesch) whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen

kdm

Angela D. Sykes

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